

# Exhibit S

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March 8, 2021

**VIA EMAIL**

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Re: **In re Valsartan, Losartan, and Irbesartan Liability Litigation**  
**Case No. 1:19-md-02875-RBK-KMW**

Counsel:

Plaintiffs write to address the ongoing unresolved deficiencies in the productions of Defendants Hetero Drugs Ltd. and Hetero Labs Ltd. ("Hetero"). The parties have engaged in numerous meet and confers in the past several weeks and while some issues have been addressed, there are still many deficiencies yet to be resolved despite numerous requests by Plaintiffs and subsequent assurances by Defendants.

**Privilege Log and Cast of Characters**

Plaintiffs wrote to Hetero on February 25, 2021 regarding the incomplete Cast of Characters that was produced with missing titles and email addresses. To date, Plaintiffs have yet to receive a response to this correspondence or an updated Cast of Characters. Please confirm that

an updated and complete Cast of Characters will be produced as soon as possible, which is also required by the Special Master's Order.

Plaintiffs also wrote to Hetero on March 4, 2021, in light of the Special Master's Order #3, to reconfirm Plaintiffs' challenge to the sufficiency of the descriptions found in the privilege logs served on behalf of Hetero. Plaintiffs requested that the parties promptly engage in a meet and confer in an effort to reach agreement that Hetero will provide proper, substantive descriptions - which has been previously documented in this litigation. Plaintiffs also reiterate the request for substantive descriptions of the contents of each document, including precise descriptions of the subject matter and the basis for the assertion of privilege, and to the extent an entire document is withheld an explanation for why the entire document is privileged. Plaintiffs have still not received a response to these requests.

#### **Document Production Issues**

On February 19, 2021, Plaintiffs wrote to Hetero regarding whether defendants conducted the required analysis of Herero's systems, applications, databases, and software and to confirm whether all contents of those that were relevant have been produced. Though the parties briefly discussed the issue during a subsequent meet and confer, Hetero has yet to provide a substantive response to this request. Please confirm whether these systems, applications, databases, and software were produced and if not, confirm they will be produced and when.

Plaintiffs' February 19, 2021 letter also listed a number of documents that were not produced correctly and had obvious production issues such as missing pages and enclosures. To date, Plaintiffs have yet to receive a response regarding the documents identified or a new production correcting the documents.

### **SOP Related Documents Requested**

Plaintiffs wrote to Defendants on February 24, 2021 requesting confirmation that Production HLL09, which was described in the Production Index as “All versions of pertinent SOP-related documents, pursuant to Plaintiffs' request” encompassed all of the missing Standard Operating Procedures (“SOPs”), quality systems manuals, and related documents that Plaintiffs have requested per our letters and meet and confers. To date, Plaintiffs have not received a response to this request either or additional productions of SOPs.

In the meantime, Plaintiffs independently confirmed that Defendant’s production of SOPs continues to be materially deficient despite several assurances from Defendants that these deficiencies would be cured, and additional documents would be forthcoming. Further, while reviewing Production HLL09, Plaintiffs have identified additional issues that need to be addressed and are discussed below.

### ***Unidentified Overlay Files***

Plaintiffs were informed by our ESI Vendor that in addition to the SOP production that was listed in the Production Index, overlay files were also produced which were not listed on the Production Index or transmittal letter and were only discovered during the ingest of the data. In addition, during our most recent meet and confer, Plaintiffs specifically discussed the manner in which overlay files should be produced and Defendants agreed. However, it does not appear that these overlay files were produced consistent with this agreement. This is a significant logistical issue and suggests that our requests for cooperation are not being fully credited or followed.

### ***Missing Versions of SOPS in Most Recent Production***

Hetero’s Production HLL09 does not appear to include all versions of the SOPs produced. For example, some SOPs end with 00 in the numbering system (QC-176-00, Bates numbered

HLL01235079 is an example) while others appear to end with 01 (QC-008-01, bates numbered HLL01235337 appears to be an example). Please confirm that for those SOPs produced ending with 01 there are no prior versions of the SOP ending in 00. In addition, the Plaintiffs do not appear to have all versions of the following SOPs:

1. HLL01236085 is version 3 of Master SOP Index for the Department of Engineering dated 1/12/21. We do not have the prior version(s).
2. HLL0123608 is version 2 of a Master SOP Index for the Department of Microbiology dated 1/27/21. We do not have the prior version(s).
3. HLL01236094 is version 2 of a Master SOP Index for the Department of Production dated 4/8/20. We do not have the prior version(s). Also, are there any subsequent versions?
4. HLL01236166 is version 2 of a Master SOP Index for the Department of Quality Assurance dated 2/16/21. Is that date correct? We do not have the prior version(s). Also, if the date is not correct, are there subsequent versions?
5. HLL01236169 is version 2 of a Master SOP Index for the Department of Quality Control dated 2/16/21. Is that date correct? We do not have the prior version(s). Also, if the date is not correct, are there subsequent versions?
6. HLL01236181 is version 1 of a Master SOP Index for the Department of Quality Control dated 7/30/20. Are there prior or subsequent versions?
7. SOPs titled Analytical Method of Verification QC047-XX. The most recent version is 05 and the effective date is 12/1/16. We note that QC047-06 "Analytical Method Verification" is specifically referenced in an index with an effective date of February 24, 2021. Bates numbered HLL01236171. Please produce QC047-06 and any prior or subsequent versions of that SOP that exist.

8. SOPs titled Trend Analysis and Handling OOT Results 01-026-XX. We do not have versions 00, 01, 02 and 03. Please confirm that there is not a more recent version than 07 dated 9/20/19.
9. SOPs titled Good Chromatographic Practices QC-176-XX. The most recent version we can find is version 05 dated 6/15/18. However, QC-176-06 is identified in HLL00819007. Please produce version 06 and any versions after 06.
10. SOPs titled Reporting of Analytical Results QC015-XX. QC015-02 dated 5/29/15 is the most recent version we can find. However, references to QC-015-03 and 04 are identified in HLL00668637 and HLL01236169. Please produce versions 03, 04 and any subsequent versions if they exist.
11. SOPs titled Retesting of Materials QC018-XX. We do not have QC018-10 with an effective date of November 5, 2018. It is specifically identified in HLL01236169. Please produce version 10 and confirm that it is the most recent version.
12. SOPs titled Sampling, Testing and Release of Materials QC004-XX. While QC004-15 with an effective date of December 24, 2018 is referenced in an index bates numbered HLL00837380, we do not have it. Please provide it and any prior or subsequent versions.
13. SOPs titled Testing and Release of In Process Finished Product Samples QC006-XX. We have been unable to locate QC006-05 after searching but note that QC006-05 is specifically referenced in the documents bates numbered HLL00842982 and HLL00837317. Please produce QC006-05 and any subsequent versions.
14. SOPs titled Usage of Liquid Sampler for Sampling of Liquid Raw Material QC025-XX. Please confirm that QC025-02 with an effective date of 5/21/15 is the most recent version. If it is not the most recent version, please provide it/them.

***Master SOP Indices Produced***

Plaintiffs have also identified several issues related to the Master SOP Indices produced. The following Master SOP Indices were provided in Defendant's most recent production: Engineering-Version 03; Microbiology-Version 02; Production-Version 02 (a prior production included a Version 01 bates numbered HLL00668259); Quality Assurance-Version 02 (a prior production included a Version 00 bates numbered HLL00668253); Quality Control-Version 02; Corporate Quality Assurance-Version 01. Based on Hetero's own internal numbering of the Master SOP Indices, it seems clear that we have not received all of them. Plaintiffs again request that all versions of all Master SOP Indices be produced.

***Document Indices Produced***

The following were provided with Defendant's most recent production and Document Indices from prior productions are also identified below:

1. Quality Control QC-SOP/118 (prior productions included QC-SOP/037 HLL01004331, QC-SOP/018 HLL01026847, QC-SOP/037 HLL00485571 and QC-SOP/059 HLL01030478);
2. Warehouse WH-SOP/008 (prior productions included WH-SOP/30 HLL01004314, WH-SOP/008 HLL01235059);
3. Corporate Quality Assurance CQA-SOP/157 (prior productions included CQA-SOP/75 HLL01004316, CQA-SOP/74 HLL01002416, CQA-SOP/81 HLL00487971, CQA-SOP/140 Hetero\_USA000163319, CQA-SOP/127 HLL457103, CQA-SOP/79 HLL00486443, CQA-SOP/88 HLL00494126, CQA-SOP/134 HLL00584452, CQA-SOP/124 HLL451049, CQA-SOP/138 HLL01068689 and CQA-SOP/121 HLL351181);

4. Engineering EN-SOP/075 (prior productions included EN-SOP/029 HLL01004319, EN-SOP/050 HLL01030466)
5. Production PD-SOP/85 (prior productions included PD-SOP/31 HLL01004325);
6. Microbiology MB-SOP/068; and
7. Quality Assurance QA-SOP/009.

Based on the above information, it does not appear that Defendants produced all of the Document Indices. Please provide all versions of the Document Indices.

***Metadata and Other Issues***

Additionally, there continue to be deficiencies in the metadata produced. Several documents contain conflicting metadata that does not comport with the actual document. These metadata issues need to be cured immediately. Below are several examples and some questions that the metadata issues raise:

1. HLL01235065 - Metadata says Corporate Quality Assurance - Unit V but the document says, "Unit Name: HLL-I, Department: Engineering". The document also shows an effective date of 9/12/20. Are there prior or subsequent versions?
2. HLL01235069 - Metadata says Corporate Quality Assurance - Unit V but the document says, "Unit Name: HLL-I; Department: Production". The document also shows an effective date of 9/2/22. Are there prior versions?
3. HLL01235076 - Metadata says Corporate Quality Assurance - Unit V but the document says, "Unit Code: HHL-I Department: Microbiology".
4. HLL01235079 - Metadata says Corporate Quality Assurance - Unit V but the document says, "Department Quality Control". Are there prior or subsequent versions?
5. HLL01235147 - Metadata shows document created on 2/19/21 but it was signed 10/10/11.



6. HLL01235065, HLL01235069, HLL01235073, and HLL01235077 Metadata says Custodian is Corporate Quality Assurance - Unit V but the document says, "Unit Name: HLL-I" and does not reference Unit V.

**Deficiencies Identified in Hetero's Prior SOP Productions**

Despite Hetero's most recent SOP production, Plaintiffs have yet to receive all of the SOPs and related documents requested in our recent letters and meet and confers. For example, despite repeated requests Hetero has still not produced any versions of the Quality Systems Manuals, other than Version 6 for Unit 5, or any emails or other documents discussing the contents and revisions, especially those made in 2018. Also, with regard to the Ready Reference of Good Manufacturing Practices, HLL00598827-951, there is one email in the entire production addressing this document, which does not seem possible. There should be emails circulating drafts, notifications to employees regarding the document, and likely other communications. In addition, the following SOPS are still outstanding.

1. SOPs titled Change Control 01-002-XX. We are missing versions 1-9, 11.
2. SOPs titled Handling of Incidents 01-005-XX. We are missing versions 1-4, 6-7.
3. SOPs titled Handling of Customer issues 01-006-XX. We are missing versions 1-4, 6-7.
4. SOPs titled Vendor Qualification 01-011-XX. We are missing versions 1-9.
5. SOPs titled Internal Audit 01-012-XX. We are missing versions 1-7, 9.
6. SOPs titled QA Release 01-017-XX. We are missing versions 1, 3-4.
7. SOPs titled Product Recall 01-018-XX. We are missing versions 1-3, 5.
8. SOPs titled Process Validation 01-022-XX. We are missing versions 1, 3-4.
9. SOPs titled Resolving OOS Results 01-027-XX. It appears that there are 7 versions of this SOP and we are unable to locate versions 1-4 and 6-7.

10. SOPs on Technology Transfer of Intermediates and API 01-034-XX. We are missing versions 1-3.
11. SOPs titled Responsibilities of Individual Departments 01-038-XX. It appears that there are four versions, and we are unable to locate them.
12. SOPs titled Analytical Method Transfer 01-040-XX. It appears that there are two versions, and we are unable to locate them.
13. SOPs titled Guidelines for Conducting Forced Degradation Studies on API 01-041-XX. It appears there is only one version and we are unable to locate it.
14. SOPs titled Qualification of Service Providers and Contract Testing Labs 01-042-XX. We are missing version 2.
15. SOPs titled Quality Risk Management 01-047-XX. We are missing version 3.

These ongoing issues have already forced the parties to reschedule depositions, which is obviously a serious issue given the timeframe in which depositions must be completed and the competing deposition schedule with the other Defendants. Please provide your availability to meet and confer regarding these deficiencies today so we can determine how we are going to proceed ahead of the conference with Judge Vanaskie this week.

Very truly yours,

A handwritten signature in blue ink, appearing to read "Adam M. Slater", written over a horizontal line.

ADAM M. SLATER